

9416 '01 FEB -2 P12:37

January 31, 2001

Dockets Management Branch  
Food and Drug Administration  
Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

**Citizen Petition**  
**Ifosfamide for Injection, USP**

Dear Sir:

Attached are four (4) copies of a Citizen Petition seeking a determination whether the listed drug, IFEX<sup>®</sup>, was withdrawn by Bristol-Myers Squibb for safety or effectiveness reasons.

If you have any questions, please call the undersigned at (708) 547-2384.

Yours Sincerely,



Tom Stothoff  
2152 W. Potomac Ave.  
Chicago, IL 60622  
Tel: (773) 862-4923

01P-0061

CP 1

**CITIZEN PETITION**

9420 '01 FEB -2 P12:37

The undersigned submits this petition under 21 CFR 10.30 and 314.122 to request the Commissioner of Food and Drugs to grant the Petitioner permission to file an Abbreviated New Drug Application (ANDA) for Ifosfamide for Injection, USP, which refers to a listed drug which has been voluntarily withdrawn from sale in the United States.

**A. ACTION REQUESTED**

This petition seeks a determination whether the listed drug, IFEX<sup>®</sup>, was withdrawn by Bristol-Myers Squibb for safety or effectiveness reasons.

**B. STATEMENT OF GROUNDS**

The reference product, IFEX<sup>®</sup>, has been discontinued by Bristol-Myers Squibb Company and is currently listed in the Approved Drug Products with Equivalence Evaluations (the "Orange Book") 20<sup>th</sup> Edition under "DISCONTINUED DRUG PRODUCT LIST". Provided in **Attachment 1** is a copy of the entry from the "Orange Book".

We intend to submit an Abbreviated New Drug Application (ANDA) for Ifosfamide for Injection, USP. The proposed product will be marketed in the identical configurations as the discontinued product, 1 gram/vial and 3 gram/vial.

**C. ENVIRONMENTAL IMPACT**

Action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR 25.31 (a).

**D. ECONOMIC IMPACT**

Not Applicable

Citizen Petition  
Ifosfamide for Injection, USP

**E. CERTIFICATION**

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all the information and views on which the petition relies, and that it included representative data and information known to the petitioner, which are unfavorable to the petition.

Tom Stothoff  
2152 W. Potomac Ave.  
Chicago, IL 60622  
Tel: (773) 862-4923

# **ATTACHMENT 1**

## DISCONTINUED DRUG PRODUCT LIST

6-95

IBUPROFENTABLET; ORAL  
IBUPROFEN

PUREPAC PHARM 400MG

600MG

800MG

SUPERPHARM 600MG

TEVA 200MG

400MG

600MG

800MG

ZENITH GOLDLINE 200MG

200MG

MIDOL  
BAYER

200MG

200MG

NUPRIN  
BRISTOL MYERS

200MG

200MG

RUFEN  
BASF

600MG

IDOXURIDINEOINTMENT; OPHTHALMIC  
STOXIL

SMITHKLINE BEECHAM 0.5%

SOLUTION/DROPS; OPHTHALMIC  
STOXIL

SMITHKLINE BEECHAM 0.1%

IFOSFAMIDEINJECTABLE; INJECTION  
IFEX

BRISTOL MYERS SQUIBB 1GM/VIAL

3GM/VIAL

N19763 001  
DEC 30, 1988N19763 002  
DEC 30, 1988IMIPRAMINE HYDROCHLORIDEINJECTABLE; INJECTION  
TOFRANIL

NOVARTIS

12.5MG/ML

N11838 002

TABLET; ORAL  
IMIPRAMINE HCL  
CHELSEA LABS

10MG

25MG

50MG

EON

10MG

25MG

LEDERLE

10MG

25MG

ROSEMONT

25MG

VANGARD

10MG

25MG

50MG

WATSON LAB

10MG

25MG

WEST WARD

25MG

50MG

JANIMINE  
ABBOTT

10MG

25MG

50MG

PRAMINE  
ALRA

10MG

25MG

N85875 001

N85878 001

N85877 001

N85200 001

N84869 002

N85133 001

N86269 001

N86267 001

N86268 001

N87776 001

FEB 10, 1982

N88036 001

NOV 03, 1982

N87619 001

FEB 09, 1982

N87631 001

JAN 04, 1982

N85220 001

N84252 002

N85221 001

N88222 001

MAY 26, 1983

N88223 001

MAY 26, 1983

N17895 001

N17895 002

N17895 003

N83827 001

N83827 002

SHIPPING  
AMERICAN PHARMACEUTICAL  
2045 CORNELL AVE  
MELROSE PARK  
(708)343-6100

SHIP DATE: 31JAN01  
ACC# 227749237

IL 60160

ACTUAL WGT: 1 LBS MAN-WT

TO:

FDA DOCKETS MANAGEMENT BRANCH  
12420 PARKLAWN DRIVE  
ROOM 1-23  
ROCKVILLE MD 20857

4433 1464 5206

**FedEx**

REF: 49407-841

**\*\*2DAY\*\***

**FRI**

CAD# 0602159 31JAN01

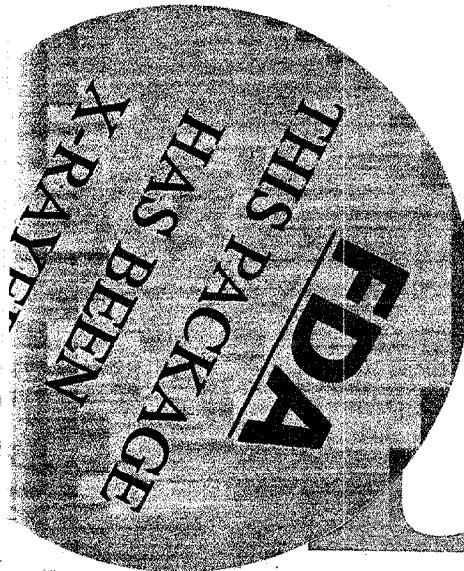
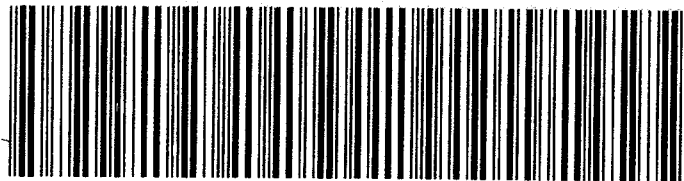
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PART # 147923 FORMAT # 077 RIT 0196